IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 5 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF SCOTT A. GUELCHER, PH.D.

Defendants Ethicon, Inc. and Johnson & Johnson ("Ethicon") submit this Reply in Support of their Motion to Exclude the Testimony and Opinions of Scott Guelcher, Ph.D. [Doc. [4573] ("Mot.")] and Memorandum of Law [Doc. [4574] ("Mem.")], (collectively, "Motion").

In its Motion, Ethicon explained that a recent article written and relied on by Dr. Guelcher—Mot. Ex. C, A. Talley, "Oxidation and degradation of polypropylene transvaginal mesh," J. Biomater. Sci., Polymer Ed. (2017) ("Talley")—suffers from a number of methodological flaws. Significantly, this is the second time Dr. Guelcher has tried—and failed—to prove that the Prolene in Ethicon mesh products oxidizes and degrades in the human body.

Dr. Guelcher previously testified that it was necessary to test his theory that Prolene degrades. Stripped of his unreliable testing, Dr. Guelcher's opinions can only withstand *Daubert* scrutiny if he grounded them in relevant, reliable scientific literature. Dr. Guelcher's failure to do so demonstrates that his degradation opinions are not the product of a reliable methodology.

I. Dr. Guelcher's Degradation Opinions Are Unsupported By Reliable Testing.

In its Motion, Ethicon explained that Talley—which Dr. Guelcher co-authored and relies on for his opinions in this litigation—is unreliable based on numerous methodological flaws. For example, with respect to Talley's intentional oxidation testing, Ethicon showed that the authors:

- recycled data from a test previously excluded by this Court as unreliable (*id.* at 5);
- failed to validate their methodology because they could not show that the oxidative medium they used to intentionally oxidize polypropylene replicated conditions in the human body (*id.* at 5-7); and
- incorporated incomplete FTIR data, which precluded the authors from ruling out the likelihood that their results were compromised by confounding factors (*id.* at 7-8).

Turning to the explant testing in the article, Ethicon demonstrated that the Talley authors:

- incorporated fictitious data points in their XPS analysis (*id.* at 9-11);
- failed to identify and adhere to a protocol for scraping the explanted fibers (*id.* at 11-12);
- failed to conduct control experiments to rule out numerous plausible alternative explanations for the oxygen the authors purportedly found on the surface of the fibers (*id.* at 12-13); and
- failed to rule out the likelihood that their XPS testing was contaminated (*id.* at 14-15).

Notably, Plaintiffs did not respond to—much less rebut—any of the methodological flaws identified by Ethicon.

Instead, Plaintiffs argue that Talley is reliable by virtue of the fact that it was published, and because the authors reported their materials and methods in the article. Plaintiffs offer no other affirmative arguments as to why the Court should conclude that Talley is reliable.

Rather, Plaintiffs claim the Court should ignore Ethicon's arguments because Ethicon merely attacks Talley's conclusions, and raises the same flaws addressed by Ethicon's experts. Plaintiffs also argue that even if the Court excludes Talley, Dr. Guelcher should still be permitted to offer his degradation opinions at trial because Talley is merely an "additional publication" supporting his opinions. As discussed below, Plaintiffs' arguments are without merit.

A. Plaintiffs failed to show that Talley is reliable.

Having failed to rebut any of the methodological flaws identified by Ethicon, Plaintiffs argue that Talley is reliable because (i) it was published; and (ii) the authors reported their

materials and methods in the article and supplemental data. *See* Resp. at 2-7. But neither of Plaintiffs' arguments is sufficient to establish that Talley is reliable.

Although Plaintiffs concede that publication is "not dispositive" as to whether an expert's opinion is reliable, (Resp. at 5), they repeatedly resort to publication as the basis for their assertion that Talley is the product of a reliable methodology, (*see id.* at 2-7). Even in proclaiming that Talley "has greater indicia of reliability" than the previously excluded version of this testing, Plaintiffs' offer nothing more than the fact that the article went "through the scrutiny of objective review by other leading biomaterials scientists[.]" *Id.* at 6.

And while Plaintiffs frame Dr. Guelcher's testimony that the Talley authors "performed additional analysis on the prior testing" as an independent basis of reliability, their own words show that this work was an effort to get the article "accepted for publication." Resp. at 6. Thus, Plaintiffs simply repeat their argument that Talley is reliable since it was published.

As Ethicon's Motion makes clear, and Plaintiffs concede, while publication is a significant factor in a court's *Daubert* analysis, it is not solely determinative as to the reliability of expert opinion. *See* Mem. at 2 n.1 (citing cases); Resp. at 5; *see also Allison v. McGahn Med. Corp.*, 184 F.3d 1300, 1313 (11th Cir. 1999) ("[I]f peer review alone was dispositive, then the *Frye* standard of general acceptability in the scientific community would have remained adequate."). As Ethicon explained, courts routinely exclude peer-reviewed literature and related opinions when errors uncovered during discovery reveal that the literature is unreliable. *Id.* (citing cases).[1] In order to satisfy *Daubert*, Plaintiffs must submit evidence showing that Talley is the product of reliable methods.[2]

[1] Plaintiffs' efforts to distinguish the cases cited by Ethicon for the proposition that courts have excluded peer-reviewed literature and related opinions ring hollow. For example, Plaintiffs essentially argue that *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 936, 939-40 (D. Minn. 2009) and *Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009) are distinguishable because the articles in those cases were

Finally, Plaintiffs' only other argument—that Talley is reliable because the authors reported their materials and methods—is meritless. *See id.* at 6-7. Indeed, all scientific articles list the materials and methods used by the authors. Plaintiffs' suggestion that any article that lists its materials and methods is inherently reliable is absurd.

B. Plaintiffs' attempt to recast Ethicon's arguments as a disagreement between experts is baseless.

In an effort to distract the Court from Talley's flaws, Plaintiffs try to frame the issue as "nothing more than Ethicon's own experts' disagreement with the conclusions in [Talley.]" Resp. at 2, 4. Plaintiffs argue that Ethicon only repeated the "rebuttal opinions of its own expert witnesses[,]" and "it is not the Court's job to determine which expert is correct[.]" *Id.* at 4.

Ethicon does not merely challenge Talley's conclusions, or ask the Court to "determine which [party's] expert is correct." *See id.* Rather, Ethicon's Motion explained in detail that the methods used in Talley were not grounded in sound scientific principles. *See* Mem. at 2-15; Resp. Ex. E, MacLean Wave 5 Report at 42-53; Resp. Ex. F, Thames Wave 5 Report at 69-78. So, while Ethicon does not dispute that the Talley authors' use of unreliable methods deprived their conclusions of validity, that does not restrict Ethicon's challenge or the criticisms of Ethicon's experts to the article's conclusions.

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even more unreliable than Talley. *See* Resp. at 5 n.18 (arguing that the *In re Viagra* court excluded an article due to errors "so severe that they required the expert to supplement his expert report," while the court in *Cedillo* excluded an article only because it had "failed to gain acceptance in the medical community and was widely-criticized"). Plaintiffs ignore the salient fact in both cases: the court excluded peer-reviewed literature and related opinions because the literature was shown to be unreliable. These rulings are consistent with decisions issued by courts around the country. *See, e.g., Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1461-64 (D. Or. 1996) (concluding that expert's opinions were unsupported because the "scientific methodology" in the studies he relied on was "disappointingly poor" and the "authors' interpretations are invalid"); *Palazzolo v. Hoffman La Roche, Inc.*, No. A-3789-07T3, 2010 WL 363834 (N.J. Super. Ct. App. Div. Feb. 3, 2010) (upholding exclusion of expert's opinion despite its publication in peer-reviewed journal). Ethicon submits that same result should obtain in this litigation.

[2] Plaintiffs claim that "for every one instance where Ethicon can point to a peer-reviewed article being scrutinized . . . there are likely hundreds of instances where the same peer-reviewed process has provided the foundation for scientific reliability." Resp. at 6. Plaintiffs failed to identify any of the "likely hundreds" of cases where a court found an opinion to be reliable based on publication alone. Nor did they point to any case holding that publication—by itself—was a sufficient basis of reliability where, as here, the article was shown to be methodologically flawed.

In addition, Plaintiffs' suggestion that the Court should disregard the methodological flaws discussed in Ethicon's Motion simply because Ethicon's experts identified those same flaws is unsupported and nonsensical. *See* Resp. at 4. This is no mere disagreement between the opinions of the parties' experts. Rather, Ethicon's Motion shows that Talley is unreliable due to a number of methodological flaws, errors, and unsupported assumptions, which are supported by citations to scientific literature and Dr. Guelcher's deposition testimony. *See* Mem. at 2-15.

Notably, Plaintiffs do not identify a single one of Ethicon's arguments that they claim is incorrect; they just say that the Court should ignore them because they correspond with the criticisms of Ethicon's experts. *See* Resp. at 3-7. But the fact that Ethicon's experts advanced similar criticisms does not somehow render Talley's methods more reliable.

Plaintiffs' argument—that an expert is immunized from a *Daubert* challenge regarding any issue addressed in the opposing party's experts' reports—has no basis in the law, and would lead to perverse results. Plaintiffs' position would force a party to choose between challenging reliability of the opposing party's expert and ensuring that its own experts satisfy the requirements of Rule 26(a)(2)(B) such that they could testify about the issue at trial. Plaintiffs' argument makes no sense.

C. The Court should not only preclude Dr. Guelcher from relying on Talley, it should exclude all of his degradation opinions in this litigation as unreliable.

Plaintiffs try to contain the damage from Dr. Guelcher's work and reliance on Talley by arguing that even the Court finds it to be unreliable, Dr. Guelcher should still be permitted testify about degradation. Specifically, Plaintiffs argue that Talley is only an "additional publication" that "supports his already-existing opinions." Resp. at 3. Ethicon disagrees.

To be clear, at a minimum, the Court should preclude Dr. Guelcher from relying on Talley to support his opinions in this litigation. Dr. Guelcher clearly relies on Talley to support

his degradation opinions, and seeks to use it as a basis to inform the jury: "I have shown that PP mesh oxidizes and degrades *in vitro*," and that an explanted mesh oxidized in the human body. Mot. Ex. B, Report at 11-12. But, as Ethicon has shown, Tally is riddled with methodological flaws. *See* Mem. at 2-15. Further, Dr. Guelcher was unable to answer even basic questions regarding the testing in Talley, (*see id.* at 4), and refused to produce the raw data on which it was based, (*id.*).[3] For all of these reasons, the Court should exclude Talley as unreliable.

Furthermore, Ethicon respectfully submits that the lack of reliability inherent in Dr. Guelcher's repeated efforts to prove his theory that Prolene is subject to oxidative degradation, coupled with Dr. Guelcher's failure to otherwise support his degradation opinions with testing or scientific literature, demonstrates that the Court should exclude his opinions in their entirety.[4]

As Dr. Guelcher's testimony demonstrates, he recognized the necessity of testing his theory that the Prolene used in Ethicon mesh products is subject to oxidation. *See* Mot. Ex. I, Guelcher 12/18/14 Dep. 107:24-108:12 ("[The] motivation for the tests was based on Ethicon's statements during trial that we had not tested it and . . . could not say definitively that Prolene polypropylene oxidizes"). Dr. Guelcher tried to prove his theory through testing twice, and failed to do so twice. Indeed, the first attempt was found to be unreliable by this Court, (*see Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *22 (S.D. W. Va. May 6, 2015)), and the second effort—Talley—is replete with methodological flaws, (*see* Mem. at 2-15).

Without the testing that Dr. Guelcher conceded is necessary to support his opinions, his degradation opinions can only be considered reliable if they are supported by reliable scientific

[3] Ethicon notes that Dr. Guelcher's refusal to produce the raw data underlying Talley, despite his admission that he could have acquired the data from his co-authors had he asked for it, is subject of a motion to compel currently pending before this Court. Defendants' Motion to Compel Discovery or in the Alternative, to Exclude Certain Opinion Testimony [Doc. 4582] and Memorandum of Law [Doc. 4584].

[4] Ethicon also notes that the egregious nature and volume of the flaws in Talley call into question the methodology underlying all of Dr. Guelcher's opinions.

literature. *See Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. 2017). But, as discussed in Ethicon's Motion, Dr. Guelcher has admitted that many of his opinions do not have a foundation in scientific literature. *See* Mem. at 15-16.

Even where Dr. Guelcher attempts to support his opinions with scientific literature, most of the papers he relies on cannot support his opinions in this litigation because they do not concern Prolene—which incorporates a specific blend of additives and antioxidants that retard oxidative degradation.[5] *See id.* at 16. For example:

- Dr. Guelcher asserts that a 2015 paper by Imel "confirmed" that the foreign body reaction causes oxidative degradation of mesh. *See* Mot. Ex. B, Guelcher Report at 10; Reply Ex. JJ, A. Imel, "In vivo oxidative degradation of polypropylene pelvic mesh," 73 Biomaterials 131-41 (2015). But he admitted that the Imel study did not address Prolene. *See* Mot. Ex. F, Guelcher 3/23/16 Dep. 134:5-11.

- Dr. Guelcher relies on a study by Wood to support his degradation opinions. *See* Mot. Ex. B, Guelcher Report at 22; Reply Ex. KK, A. Wood, "Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient," 24 J. Mater. Sci. Mater. Med. 1113 (2013). He has acknowledged at trial, however, that the study addresses hernia meshes, not meshes used in the pelvic floor. *See* Mot. Ex. E, *Huskey* 8/25/2014 Trial Tr. 183:20-21. He also admitted that nothing in the Wood study suggests that it analyzed Prolene. *Id.* at 183:22-23.

- Dr. Guelcher states that Costello found that polypropylene meshes degrade and fail based on "comparisons made between pristine and explanted samples via molecular weight, SEM imaging, and compliance testing." Mot. Ex. B, Guelcher Report at 22-23. This assertion is incorrect. Neither of the Costello articles he cited reported the molecular weight of pristine or explanted mesh. Reply Ex. LL, C. Costello, "Materials characterization of explanted hernia meshes," 83B J. Biomed. Mater. Res Part B: Appl Biomater 44 (2007); Reply Ex. MM, C. Costello, "Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient," 14 Surg. Innov. 168 (2007). In addition, the "Materials Characterization" paper analyzed only mesh manufactured by Bard, and not the Prolene at issue in this litigation. And while the "Single Patient" paper included an Ethicon hernia mesh, the paper only reported evidence of oxidation and degradation of a Bard mesh, and reported no evidence of degradation for the Ethicon mesh. Reply Ex. MM, Single Patient at 172-75.

[5] As noted in the Motion, Ethicon is fully aware of the Court's views as to Ethicon's position that Prolene is unique. *See* Mem. at 3 n.2. Again, Ethicon respectfully submits that its position is corroborated by the words of Plaintiffs' own experts. *Id.* Indeed, Dr. Guelcher admits that Prolene is different than other forms of polypropylene. Mot. Ex. F, Guelcher 3/23/16 Dep. 87:23-88:9.

- Dr. Guelcher relies on a study by Fayolle to support his opinion that polypropylene is subject to embrittlement due to oxidative degradation, and uses charts from Fayolle in his expert report. Mot. Ex. B, Guelcher Report at 5-7; Reply Ex. NN, B. Fayolle, "Oxidation induced embrittlement in polypropylene—a tensile testing study," 70 Polymer Degradation & Stability 333 (2000). But Dr. Guelcher admitted that Fayolle did not address polypropylene treated with antioxidants, like Prolene. Reply Ex. OO, Guelcher 3/25/14 Dep. 93:6-94:11. He also admitted that he was unaware of *any* study of polypropylene treated with antioxidants that would support his embrittlement opinions. *Id.* at 94:6-11; Mot. Ex. F, Guelcher 3/23/16 Dep. 72:11-73:23.

- Dr. Guelcher points to a paper he co-authored to establish the presence of inflammatory cells and oxidative enzymes on or near the surface of polypropylene fibers. Mot. Ex. B, Guelcher Report at 9-10; Reply Ex. PP, Iakovlev, "Degradation of polypropylene in vivo: a microscopic analysis of meshes explanted from patients," J. Biomed. Mater. Res. Part B (2015). Neither Dr. Guelcher's discussion of the study nor the image he reproduced from it actually address Prolene. *See* Mot. Ex. B, Guelcher Report at 9-10, fig. 7.

- Dr. Guelcher relies on a 1976 study by Liebert to support his opinion that polypropylene is subject to oxidative degradation. Mot. Ex. B, Guelcher Report at 6-7, 113-14; Reply Ex. QQ, T. Liebert, "Subcutaneous implants of PP filaments," 10 J. Biomed. Mater. Res. 939 (1976). Not only did Liebert not analyze Prolene, but Dr. Guelcher admitted that the study actually found that antioxidants are effective at preventing polypropylene degradation. *See* Reply Ex. OO, Guelcher 3/25/14 Dep. 73:16-74:1.

And while some of the articles Dr. Guelcher cites address Prolene, they do not stand for the proposition that Prolene degrades *in vivo*. Mem. at 16 (discussing Moalli and Clave articles).

As none of the literature on which Dr. Guelcher relies supports his opinion that Prolene degrades *in vivo*, the Court should exclude his degradation opinions as unreliable.[6]

II. The Court Exclude Dr. Guelcher's Alternative-Design Opinions.

A. None of Dr. Guelcher's Proposed Alternative Procedures or Materials Constitutes An Alternative Design to the Ethicon Mesh Products At Issue.

As Ethicon explained in its Motion, although Dr. Guelcher offers several procedures and biological grafts as alternatives to Ethicon mesh products, none of his proposals constitute

[6] Plaintiffs contend that Dr. Guelcher should be permitted to base his opinions on certain internal Ethicon documents because "[t]hese same Ethicon studies have been admitted at trial and have been discussed by several experts in this litigation for both Plaintiffs and Ethicon." Resp. at 8. Plaintiffs misconstrue Ethicon's position. Ethicon did not argue that the documents are *per se* inadmissible. *See* Mem. at 17. Rather, Ethicon showed that Dr. Guelcher's reliance on those documents is misplaced because they do not establish that Prolene degrades *in vivo*. *See id.*

alternative designs. *See* Mem. at 18. Specifically, Ethicon showed (i) different *procedures*—like the Burch and needle suspension procedures advocated by Dr. Guelcher—are not alternative *designs* to Ethicon mesh products; and (ii) all of the biological grafts he proposed have different implantation procedures and different functionality than Ethicon mesh products. *Id.*

B. Dr. Guelcher's proposed biological grafts are not alternative designs to Ethicon mesh products.

Plaintiffs failed to address Ethicon's arguments that biological grafts are not alternative designs to Ethicon's mesh products. *See* Resp. at 8-10. Thus, Plaintiffs implicitly concede that autografts are not medical devices, and that the implantation procedures and functional characteristics of all of Dr. Guelcher's proposed biological grafts are distinct from Ethicon mesh products. *See* Mem. at 18. Because Plaintiffs made no effort to show that biological grafts are proper alternative designs, the Court should preclude Dr. Guelcher from testifying about biological grafts at trial for the reasons stated in Ethicon's Motion.

C. This Court has already rejected Plaintiffs' argument that Dr. Guelcher's proposed alternative procedures and materials constitute an alternative design.

This Court has already rejected Plaintiffs' argument that Dr. Guelcher's proposed alternative procedures and materials constitute an alternative design. *See Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942-44 & n.2 (S.D. W. Va. 2017).

Plaintiffs make a feeble and disingenuous attempt to distinguish this ruling, claiming that this Court's ruling in *Mullins* is a "West Virginia-specific determination" that leaves the ultimate decision regarding alternative design to the jury. *See* Resp. at 8-9. This is simply untrue.

There is no basis to limit the Court's rulings regarding what constitutes an alternative design to West Virginia. Plaintiffs ignore the fact that the Court's decision was based, in relevant part, on opinions issued by the Fourth and Fifth Circuits, not West Virginia state law. *See*

Mullins, 236 F. Supp. 3d at 942-44 & n.2 (discussing *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) and *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999)).

Moreover, this Court's ruling in *Mullins* is consistent with decisions from courts across the country. *See, e.g., Hilaire v. DeWalt Indus. Tool Co.*, 54 F. Supp. 3d 223, 248 (E.D.N.Y. 2014); *Schmidt v. C.R. Bard, Inc.*, 2013 U.S. Dist. LEXIS 101963, at *6 (D. Nev. July 22, 2013); *Michael v. Wyeth, LLC*, 2011 WL 2150112 at *11 (S.D. W. Va. 2011).[7] Plaintiffs did not identify any authority to the contrary.

In addition, Plaintiffs misinterpreted the *Mullins* decision as it relates to Ethicon's Motion. Plaintiffs focus on the Court's finding that alternative design becomes a question of fact after a plaintiff satisfies her burden to present "sufficient evidence to identify a comparable product or design concept[.]" Resp. at 9. In so doing, Plaintiffs ignored the fact that the Court expressly ruled that "polypropylene suture is not an alternative, feasible design for the TVT device" at issue in that case, and that "plaintiffs must provide evidence of an alternative, feasible design for the product at issue," not an alternative procedure. *Mullins*, 236 F. Supp. 3d at 944.

As none of the alternative procedures or materials proposed by Dr. Guelcher constitute alternative designs, the Court should preclude him from offering any alternative-design opinions.

D. Dr. Guelcher's alternative-design opinions are unreliable.

As Ethicon explained in its Motion, the Fourth Circuit's decision in *Nease* affirms that an expert cannot offer an opinion regarding alternative design without showing, through reliable testing or scientific literature, that the proposed alternative is actually safer and as effective as the product at issue. *See* Mem. at 19. Specifically, Ethicon showed that the Court should exclude Dr. Guelcher's alternative design opinions because he failed to base his alternative-design opinions

[7] The Court recently affirmed the broad applicability of its *Mullins* ruling, holding "alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists." *See* Mem. Op. & Order (*Daubert* Mot. re: Nathan Goodyear), *In re: Ethicon, Inc.*, No. 2:12-md-02327 at 6 (S.D. W. Va. Mar. 29, 2017) [ECF 3540].

on testing or literature demonstrating that his proposed alternatives are safer than, and at least as effective as, Ethicon mesh products in treating SUI or POP. *See id.*

Plaintiffs do not dispute that Dr. Guelcher did not test his proposed alternatives. Instead, they argue that he based his opinions on his "experience in biomaterials, Ethicon's internal studies on mesh and Prolene specifically, all of the clinical literature about the foreign body response to polypropylene sutures and mesh, the many clinical papers comparing the use of biologics and other suture repairs to that of polypropylene mesh, and his own experience, training, and expertise in developing new products to be used inside the human body." Resp. at 10. As discussed below and in Ethicon's Motion, Plaintiffs' argument is belied by Dr. Guelcher's report and a substantial body of scientific literature.

1. Under *Nease*, an expert cannot offer alternative-design opinions at trial without test data or medical literature showing that the proposed alternatives are safer and at least as effective as the product at issue.

Although Plaintiffs advanced a number of arguments in an effort to distinguish *Nease*, their arguments are unavailing. For example, Plaintiffs' claim that the Court should ignore the teachings of *Nease* because (i) "*Nease* was . . . decided under W. Va. law and cannot be applied to the entire Wave of cases before the Court," and (ii) testing is not an absolute requirement under *Daubert*. Resp. at 9 & n. 33.

Although West Virginia supplied the underlying law in *Nease*, the Fourth Circuit based its decision regarding the reliability of expert testimony on long-standing precedent from the U.S. Supreme Court and Fourth Circuit, as well as decisions from sister circuits. *See Nease*, 848 F.3d at 229-33 (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604 (8th Cir. 2011); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665 (6th Cir. 2010); *Oglesby v. Gen.*

Motors Corp., 190 F.3d 244 (4th Cir. 1999)). Plaintiffs' assertion that the logic of *Nease* ends at borders of West Virginia is without merit.

In addition, while Ethicon agrees with the Fourth Circuit's affirmation that an "especially important factor for guiding a court in its reliability determination is whether a given theory has been tested," (*Nease*, 848 F.3d at 231), Ethicon never argued that testing is an absolute precondition to the admissibility of expert testimony under *Daubert*, (*see* Mem. at 19). Rather, Ethicon argued unambiguously that Dr. Guelcher's alternative-design opinions are unreliable because he failed to show that his proposed alternatives are safer and as effective as Ethicon mesh products using reliable testing *or* scientific literature. *See* Mem. at 19. Plaintiffs' attempt to re-cast Ethicon's position to fit their argument is a red herring.

Nothing in Plaintiffs' response shows that Dr. Guelcher's proposed alternatives are grounded in a reliable methodology.[8] Thus, the Court should exclude Dr. Guelcher's opinions.

2. Neither Dr. Guelcher nor Plaintiffs identified any scientific literature showing that his proposed alternative procedures and materials are safer and at least as effective as Ethicon mesh products in treating SUI and POP.

Plaintiffs claim that Dr. Guelcher's opinions regarding alternative designs are reliable because they are "firmly grounded in the clinical and scientific literature," and "based on measureable data with repeatable results from countless scientific experiments, decades of clinical usage and scientific study, and many papers that are recounted in his report." Resp. at 10. Tellingly, Plaintiffs fail to identify a single document that actually supports Dr. Guelcher's alternative-design opinions. In fact, none of the materials to which Dr. Guelcher cites demonstrates that any of his proposed alternative designs are safer than, or as effective as, Ethicon mesh products at treating SUI or POP.

[8] Plaintiffs made no effort to argue that PVDF constitutes an alternative design to Ethicon mesh products. Resp. at 8-10. Nor could they. None of the documents Dr. Guelcher cites regarding PVDF shows that a PVDF mesh would be safer or as effective as Ethicon mesh products at treating SUI or POP. *See* Mot. Ex. B, Guelcher Report at 27-28.

Dr. Guelcher did not cite any authority that supports his assertion that suture-based repairs like the Burch procedure are safer or as effective as Ethicon mesh products. *See* Mot. Ex. B, Guelcher Report at 25-28. Rather, he refers only to a handful of articles that address the foreign body reaction to sutures and mesh—not whether suture-based repairs are safer or as effective as Ethicon mesh products. *See id.* Like the expert in *Nease*, despite this lack of support, Dr. Guelcher "simply proclaims" that treatments involving sutures are "preferred" because they elicit "less persistent" foreign body reaction than mesh, and "do not present the risk of mesh-related complications." *Id.* at 26.

And while Dr. Guelcher points to three studies to support his opinion that biological grafts are safer and as effective as Ethicon mesh products, a review of these studies demonstrates that they simply do not support his opinion. *See id.* at 26-27 & nn. 126-30; *see also* Reply Ex. RR, S. Crivellaro, *et al.*, "Transvaginal Sling Using Acellular Human Dermal Allograft: Safety and Efficacy in 253 Patients, 172 J. Urology 1374-78 (2004); Reply Ex. SS, S.L. Brown & F.E. Govier, "Cadaveric Versus Autologous Fascia Lata for the Pubovaginal Sling: Surgical Outcome and Patient Satisfaction," 164 J. Urology 1633-37 (2000); Reply Ex. TT, B.J. Flynn & W.T. Yap, "Pubovaginal Sling Using Allograft Fascia Lata Versus Autograft Fascia for All Types of Stress Urinary Incontinence: 2-Year Minimum Followup," 167 J. Urology 608-12 (2002).

Dr. Guelcher made no effort to support his proposed alternative designs for Ethicon mesh products used to treat POP. Indeed, the Brown and Flynn studies do not address devices used to treat POP. While some of the procedures discussed in Crivellaro involved both POP and SUI repairs, the study did not actually report on complications or efficacy with respect to POP. *See* Reply Ex. RR, Crivellaro. Since none of the studies Dr. Guelcher cites address POP, he should not be permitted to offer alternative designs as to Ethicon mesh products used to treat POP.

As to Dr. Guelcher's proposed alternatives for SUI repairs, the only sources he relies on for his opinions regarding biological grafts are three dated and short-term studies which offer no support for the long-term safety and efficacy of the grafts. By the authors' respective admissions, each of these studies is short-term. Reply Ex. RR, Crivellaro at 1377 ("Longer followup and a randomized trial comparing Repliform to other materials used in sling procedures are needed."); Reply Ex. TT, Flynn at 612 (results do not justify adoption of different pubovaginal sling material "until long-term data are available and reproducible by multiple groups"); Reply Ex. SS, Brown, at 1636 (results must "remain consistent at longer followup"). Given that none of the studies is recent—the latest published in 2004—Dr. Guelcher's decision to base his opinions on short-term studies speaks volumes as to the dearth of scientific support for his opinions.

Since Dr. Guelcher cannot say that his alternatives offer viable long-term safety and efficacy rates, he should not be able to offer his proposals as alternative designs to Ethicon mesh products.

Highlighting the weakness of Dr. Guelcher's methodology is the fact that the author of one of these studies—Dr. Brian Flynn—opines in this litigation that biological grafts are not safer or more effective than Ethicon mesh products. *See* Reply Ex. UU, Expert Report of Brian J. Flynn, M.D. (TVT) ("Flynn TVT Report"); Reply Ex. VV, Expert Report of Brian J. Flynn, M.D. (Prolift) ("Flynn Prolift Report"). Based on his experience and review of the literature in the fourteen years after the publication of the article Dr. Guelcher cites, Dr. Flynn now concludes that while biological grafts can be used to treat SUI and POP, they do not have better safety and efficacy rates than Ethicon mesh products. *See* Reply Ex. UU, Flynn TVT Report at 12 (concluding that allografts "do not have the long-term durability of synthetic material," and "have been shown to degrade and decompose in patients on follow up."); Reply Ex. VV, Flynn

Prolift Report at 12 (explaining that systematic literature reviews have shown that biological grafts cause exposure, wound complications, and dyspareunia at rates comparable or even exceeding synthetic mesh). Dr. Flynn also observes that biological grafts present risks of unique complications (including tissue rejection and the transmission of diseases) that are not associated with synthetic mesh. Reply Ex. VV, Flynn Prolift Report at 13.

Finally, as discussed below and in Ethicon's Motion, in basing his opinions on three relatively old, short-term studies, Dr. Guelcher ignored the substantial body of literature showing that his proposed alternatives are not safer than, or as effective as, Ethicon mesh products.

3. Dr. Guelcher neither acknowledged nor accounted for the substantial body of scientific literature contradicting his alternative-design opinions.

In its Motion, Ethicon explained that a substantial body of scientific literature refutes Dr. Guelcher's alternative-design opinions. *See* Mem. at 19-20 & nn. 13-15. Indeed, Ethicon identified several studies tending to rebut Dr. Guelcher's alternative-design opinions. *See id.* While an expert's opinions need not align with every piece of scientific literature to pass *Daubert* scrutiny, as this Court has recognized, if "the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *See Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *11 (S.D. W. Va. Sept. 29, 2014).

In their response, Plaintiffs made no effort to distinguish or dispute the findings of any of the literature identified by Ethicon. *See* Resp. at 8-10. Nor did Plaintiffs point to any specific literature that actually demonstrates that any of Dr. Guelcher's proposed alternatives is safer than and as effective as Ethicon mesh products in treating SUI or POP. *See id.*

For these reasons, as well as those identified in Ethicon's Motion, the Court should preclude Dr. Guelcher from offering opinions regarding alternative designs at trial.

CONCLUSION

For these reasons, as well as those articulated in the Motion, Ethicon respectfully requests that the Court grant its Motion to Exclude the Opinions and Testimony of Dr. Scott Guelcher.

Respectfully submitted,

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1800
dthomas@tcspllc.com

/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
601.985.4523
christy.jones@butlersnow.com
(601) 985-4523

COUNSEL FOR DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 5 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I hereby certify that on September 21, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas

David B. Thomas (W.Va. Bar #3731)
Philip J. Combs (W.Va. Bar #6056)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800

COUNSEL FOR DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON